3M
Health Care
3M Center

St. Paul, MN 55144-1000

Quality Improvement Project

Project Title	Use of a passive disinfection device to improve the disinfection compliance of connectors and to reduce Blood Stream Primary Infection associated with central catheters (CLABSI) in an adult oncology hospital.
Principal Investigator	[redacted]
Facility	[redacted]
Ethics Committee	[redacted]
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Contract Research Organization: [redacted]

Approver List (3M Approvers Only):

Signer	Role	Date Signed
[redacted]		

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1. Introduction

A compliance improvement study to reduce Central Line Associated Blood Stream Infection (CLABSI) using a passive disinfection device in an oncological population in Brazil.

Although many efforts have been focused on reducing the level of hospital-acquired infections, central line associated bloodstream infections (CLABSIs) remain a serious complication in hospitalized patients, leading to significantly longer hospital stays, morbidity, and mortality for affected patients. In a case-control study in Brazil, for example, the incremental length of stay for adult ICU patients with CLABSI compared to those without CLABSI averaged 19.6 days, while incremental costs for one CLABSI infection totaled US $89,886 (Dal Forno, et al. 2012.)

An emerging issue in Brazil is the shifting etiology of CLABSI infections. A significantly higher percentage is attributed to Gram-negative bacilli compared to the US and other northern countries (Marra et al, 2011.) Even so, coagulase-negative *Staphylococci* have traditionally been the most prevalent causative organisms for this type of infection. However, 2015 surveillance data from the Brazilian National Health Surveillance Agency (ANVISA) showed for the first time that *Klebsiella pneumoniae,* a Gram-negative organism, caused the highest percentage of CLABSIs in adults. *K. pneumoniae* was identified in 16.9% of infections, while coagulase-negative *Staphylococcus* was ranked second at 16.5%. *Acinetobacter* species and *Pseudomonas aeruginosa,* two other Gram-negative organisms, caused the 4th and 5th highest number of CLABSIs, respectively (ANVISA, 2016.) A predominance of Gram-negative organisms causing catheter-related blood stream infections was also noted from a multi-site study in Sao Paulo, Brazil. The top three causative organisms for CR-BSIs were *A. baumannii* (19%), *P. aeruginosa* (15.2%), and *K. pneumoniae* (15.24%) (Bicudo et al, 2011.)

The increase in Gram-negative organism CLABSI infections is concerning, as several are already highly resistant to specific classes of antibiotics. 2015 ANVISA surveillance data showed that 77.4% of the *Acinetobacter* strains and 39.1% of *P. aeruginosa* strains from CLABSI infections were resistant to carbapenems, while 43.3% of *K. pneumoniae* strains were resistant to both carbapenems and to 3rd and 4th generation cephalosporins (ANVISA, 2016.)

Implementation of a set of evidence-based practices, or bundles, both for insertion of Central Venous Catheters (CVC) and for CVC maintenance, is recommended to combat CLABSI infection rates. The CLABSI Maintenance Bundle includes appropriate hub disinfection in addition to administration set changes and daily review of line necessity with timely removal (Marshall et al., 2014.) Implementation of the bundles has lowered CLABSI infection rates (Grigonis et al, 2016.) However, compliance to traditional “scrub the hub” disinfection methods are low (Cameron-Watson, 2016.) The disinfecting barrier cap was developed to remove operator variability with scrub the hub and improve compliance to disinfection

procedures. Increased compliance can lead to reductions in CLABSI rates (Danielson et al, 2014; Merrill et al, 2014, Morneau et al, 2015; Ramirez et al, 2012; Sweet et al, 2012.)

The objective of this quality improvement project is to replicate hub disinfection compliance studies in a Brazilian model, where etiology of infections differ from many northern countries. Completing this quality improvement project will help determine if there is a corresponding drop in CLABSI when using disinfecting barrier caps as in seen in the studies referenced above, given the differences in causative organisms for CLABSI.

2. Project Objectives and Purpose

(1) To examine healthcare professionals' compliance to needleless connector antisepsis with the barrier cap protocol compared to the previous "scrub the hub" protocol;

(2) To establish the effect of the disinfecting barrier cap on the rate of CLABSI per 1,000 intravenous line days among the designated patient population.

Catheter-associated urinary tract infection (CAUTI) rates and ventilator-associated pneumonia (VAP) rates during the intervention period will also be reviewed to control for possible seasonal or environmental effects that may also influence CLABSI and hospital infection rates overall.

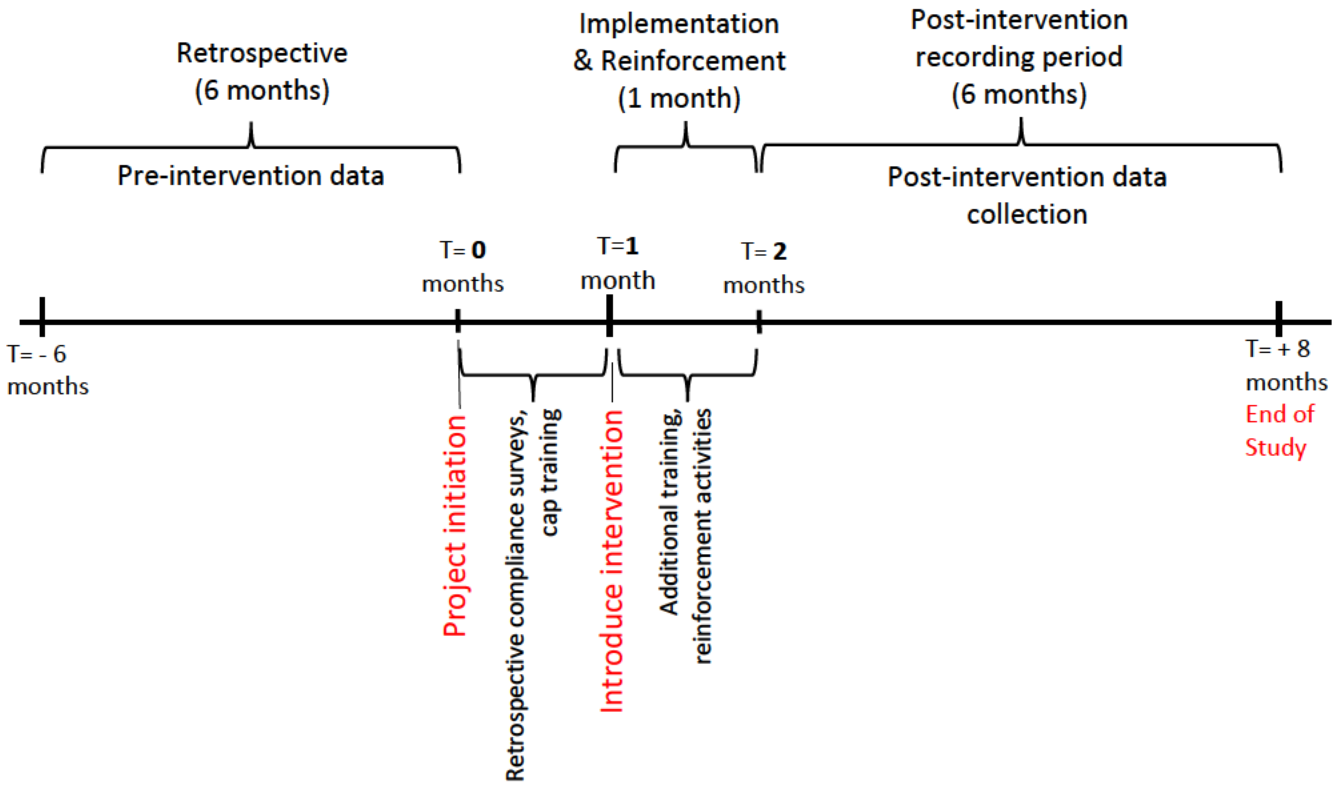
Data for CAUTI and VAP will be available for intensive care units (ICUs), as collection is only mandatory for ICUs in Brazil. For this study, the definition of CLABSI is that used by the National Healthcare Safety Network **(**NHSN). The definitions of CAUTI and VAP are those used by The Brazilian National Health Surveillance Agency (ANVISA.)

During the project, changes to the insertion and maintenance infection reduction bundles for CLABSI prevention in designated intervention units will be limited to the implementation of the disinfecting barrier cap in the place of current method, and cap training/feedback procedures. These procedures include, but are not limited to, visual aids designed to increase adherence to the new procedure, and feedback after compliance audits – which is required since uncapped ports may present a risk to the patient.

Additionally, any changes to infection reduction bundles for CAUTI and VAP will be avoided during the study to allow these measurements to be used as controls. If any changes to infection reduction practices for CAUTI and VAP are made during the duration of the project, these will be noted and a determination will need to be if those infection rates are still appropriate to use as controls.

3. Project Design

A quasi-experimental before-and-after project with a seven -month intervention phase.


Retrospective
(6 months)
Pre-intervention data
Implementation
& Reinforcement
(1 month)
Post-intervention
recording period
(6 months)
Post-intervention data
collection
T= 0
months
T=1
month
T= 2
months
T= - 6
months
T= + 8
months
End of
Study
Project initiation
Retrospective compliance surveys,
cap training
Introduce intervention
Additional training,
reinforcement activities

Overview

Project Initiation (Month #1)

- Give consent form (Responsibility Term) to healthcare professionals participating in retroactive compliance survey (PI, site staff)
- Complete retroactive scrub-the-hub compliance survey (care givers)
- Multiple teaching sessions on project objectives, use of the disinfecting barrier caps (PI, study staff)
- Begin recording monthly CLABSI, CAUTI, & VAP data for designated wards from the 6-month pre-intervention period
- Stock caps in designated locations in assigned intervention wards to prepare for introduction (PI, study staff)

Introduce Intervention (Month #2, Day 1)

- Place disinfecting cap strips on IV poles near ICU beds containing patients with central IVs (PI/study staff/care assistants)
- Introduce individual disinfecting caps in non-ICU intervention wards in appropriate areas to be utilized for other patients that meet acceptance criteria for the study.
- Begin use of caps in assigned units (care givers)

Cap Implementation and Reinforcement (Month #2)

- Daily stocking of cap strips and individual caps, as appropriate, in intervention wards (care assistants)
- Measure compliance with observation form for disinfecting cap use 3 times per week. Document number of ports being used for continuous infusion, and any misuse of disinfecting caps as listed in Section 4.4.2. Notify the Nurse Assistance Unit after the end of the audit about any uncapped needleless connectors or misused caps for any necessary corrections (PI, study staff)
- 2 weeks after intervention: team training and compliance improvement brainstorming
- Implement suggestions to improve compliance, which could include placement of disinfecting cap use posters, re-training, sharing updates on disinfecting cap compliance data, and/or other interventions deemed appropriate arising from the brainstorming process (PI, study staff).

Recording Period (Months 3-8)

- Daily stocking of cap strips or individual caps in intervention units, as appropriate (care assistants)
- Continue use of disinfecting caps (care givers)
- Measure compliance with disinfecting cap use weekly, with observation form. Document number of ports being used for continuous infusion, and any misuse of disinfecting caps as listed in Section 4.4.2. Notify the Nurse Assistance Unit after

the end of the audit about any uncapped needleless connectors or misused caps for any necessary corrections (PI, study staff)
- Enter weekly compliance observations into electronic database
- Complete documentation of pre-intervention CLABSI, CAUTI, & VAP data
- Document monthly post-intervention CLABSI, CAUTI, & VAP data by ward

End of Study (After Month-8)
- Remove disinfecting barrier cap stock from assigned wards
- Complete documentation of post-intervention CLABSI, CAUTI, & VAP data
- Complete entry of weekly compliance observations into electronic database
- Data analysis by designated group

3.1 Primary and Secondary Endpoints

3.1.1 Primary Endpoint: **The rate of compliance to hub disinfection protocol**.

3.1.2 Secondary endpoints (all collected from aggregate hospital surveillance data):

3.1.2.1 **Rate of central line associated bloodstream infections (CLABSIs) per 1,000 central line days**

3.1.2.2 **Catheter-Associated Urinary Tract Infection (CAUTI) per 1,000 catheter days and Ventilator-Associated Pneumonia (VAP) per 1,000 ventilator days (controls)**

3.2 Subjects

Note: During the project, no individual patient health information will be collected.

3.2.1 Subject Inclusion Criteria

- Adult patients admitted to the participant oncologic hospital
- Adult patients in the assigned intervention units during the seven-month intervention period who require needleless connectors for CVC IV tubing access.

  The types of central venous catheters accessed by needleless connectors in this study include:
  - Non-tunneled CVCs percutaneously inserted into the internal jugular, subclavian, or femoral veins
  - Tunneled CVCs implanted in the internal jugular, subclavian, or femoral veins
  - Peripherally inserted central catheters (PICCs) inserted percutaneously into the basilic, brachial, or cephalic vein and entering the superior vena cava

- Patients without CVC IV access who are using a three-lumen dialysis catheter with a needleless connector on the third lumen. If a patient with a dialysis catheter but without CVC IV access presents an infection, the infection will be counted nonetheless due to the impossibility of separating it from the other infections. Dialysis catheters will only receive the disinfecting cap if the dialysis catheter contains a third lumen with a needleless connector attached.
- Patients meeting inclusion criteria and who are subsequently transferred out to a unit of the hospital not covered by the study will have disinfecting caps removed immediately before transfer and will not be included in the compliance audits during their period out of the study unit. They will continue to be evaluated when they return to the study unit if that ever occurs. Therefore, if these patients are then transferred back from those units (includes HSR units such as: Surgical Center, Nuclear Medicine, Radiotherapy, Center of Diagnosis and Imaging, and Chemotherapy; and other hospitals of the complex: [redacted]), disinfecting caps will be re-introduced upon patient transfer, and patients will again be included in the study.

3.2.2 Subject Exclusion Criteria

- Adult patients admitted to the participant oncologic hospital during the seven-month intervention period that do not require needleless connectors for CVC IV access during their hospital stay.
- Patients without CVC IV access who are using two-lumen dialysis catheters. If such a patient presents an infection, it will be counted nonetheless due to the impossibility of separating it from the other infections. Dialysis catheters will only receive the caps if the dialysis catheter contains a third lumen, with a needleless connector.
- Patients may be excluded from the study at the investigator's discretion in case of unforeseen circumstances.
- Additionally, patients who require needleless connectors for CVC IV access, who are subsequently transferred to a different institution or to a different ward/unit that has not been trained in the use of disinfecting barrier caps, will be excluded from the study beginning at the time of transfer. For these patients, the disinfecting caps will be removed immediately before the patient is transferred to a unit of the hospital not covered by the study (includes HSR units such as: Surgical Center, Nuclear Medicine, radiotherapy, diagnostic center and imaging, and chemotherapy); and other hospitals of the complex: [redacted]). In the hospital units (wards) not covered

by the study, the procedure used for the disinfection of the catheters will be the standard procedure of the hospital (scrub-the-hub) instead of the disinfecting caps.

3.2.3 Study Approval

As the study utilizes commercialized product, and is being implemented as a quality improvement procedure throughout the patient population, approval for implementation will be requested from the institution's Ethics Committee. During the project, no individual patient protected health information will be collected.

4. Disinfecting Barrier Cap Information

4.1 Name, Description and Intended Use

The 3M™ Curos™ Disinfecting Cap for Needleless Connectors (the "disinfecting barrier cap") is intended for use on swabbable luer-access valves as a disinfecting cleaner prior to line access and to act as a physical barrier to contamination between line accesses. The disinfecting barrier cap will disinfect the valve one (1) minute after application and act as a physical barrier to contamination for up to seven (7) days (168 hours) if not removed.

The 3M™ Curos™ Disinfecting Cap for Needleless Connectors is commercially available and will be used per product labeling.

4.2 Risk/Benefit Summary

Minimal adverse health effects are anticipated for the participants in this quality improvement project. All required preclinical safety studies (toxicology studies) have been completed. Benefits may include increased compliance with institutional disinfection protocols for needleless connectors and reduced risk of patient exposure to infection. In addition, use of disinfecting barrier caps allow for visual, auditable confirmation of compliance to disinfection protocols for needleless connectors, which is not possible with the scrub-the-hub disinfection method.

Risks identified in the Risk Management Report include:

- Not sterile (loss of efficacy resulting in possible infection or contamination)
- Device is not secure (not applying fully)
- Choking
- Device is placed on the wrong connection
- Degradation of associated device/connector (crack and leak)
- Flammable
- Toxicologically hazardous material (70% IPA) enters the blood stream

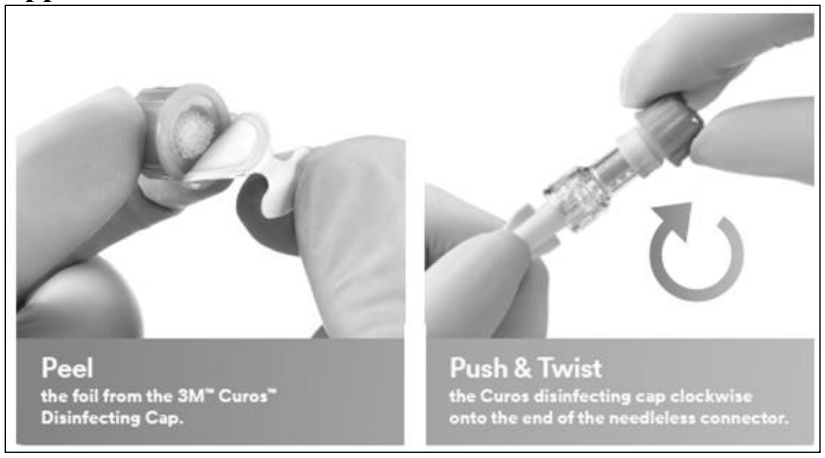
All known risks, both in normal and fault conditions, along with the overall residual risk, have either eliminated or adequately mitigated, considering current state of the art. The risk management for Curos™ Disinfecting Port Protectors revealed no significant hazards that could endanger the user, if the product is used as intended and under recommended conditions.

4.3 **Product Use**

The disinfecting barrier caps will be used on needleless connectors for Central Venous Catheter IV tubing access in the designated hospital units during the seven month intervention period.

Disinfecting barrier cap strips will be used in ICU wards, and individual disinfecting barrier caps will be used in other wards for patients that meet inclusion criteria for the study.

Application Instructions



- If the needleless connector is visibly soiled with blood or body fluids, clean with swab before using cap.
- Do not use cap if seal is broken, torn, punctured, or if sponge appears dry.
- Cap must remain on needleless connector for a minimum of one (1) minute and may remain on for seven (7) days if not removed.
- The needleless connector can be accessed immediately after removing the Curos disinfecting cap that has been in place for a minimum of one (1) minute.
- Always place a new Curos disinfecting cap on needleless connector after each use.
- Dispose of the Curos disinfecting cap after each use.
- WARNING: Use only on needleless connectors.
- CAUTION: Potential choking hazard.

- CAUTION: Use clinical judgment to assess the risks versus benefits of using this product on premature infant populations. Safety and consequences related to IPA have not been established or determined in the toxicology literature for this population.

Access instructions after removal of cap

- After disinfecting barrier cap is removed, no dry time is required before accessing the line.
- If performing sequential accesses with needleless connectors, additional "scrub-the-hub" steps (between every catheter access) are not mandatory as per the institution's current standard of practice.
- Disinfecting barrier caps will be used to disinfect needleless connectors during the project intervention period. Disinfecting barrier caps are one-time use only, and should be discarded after being removed from a needleless connector.

4.4 Adverse Events or Misuse

4.4.1 As this is a quality improvement study focused on the process of the health care professional, no individual patient data, including adverse events, will be recorded. However, if the investigator feels that a device-related adverse event does occur, he/she is responsible to report it through the existing 3M Medical Complaint system described in Section 4.4.3 below.

4.4.2 In addition, instances of product misuse may also be reported to the 3M Medical Complaint system described in Section 4.4.3 below. Potential scenarios of misuse may include:

4.4.2.1 Use on wrong connector

- Open system of vein peripheral catheter
- Open system of arterial peripheral catheter
- Open infusion system of central catheter
- Directly on dialysis catheter hub
- Directly on central catheter hub
- Inappropriate connector (for instance, Tego for dialysis)

4.4.2.2 Device not secure (not applied fully)

4.4.2.3 Other (describe):

4.4.3 The 3M Medical Complaint System can be reached by dialing the Help Line Hospitalar: 0800 13 23 33, or by email via falecoma3m@mmm.com.

5. Statistics

5.1 Data Sets Analyzed

Data from all compliance audits within the six-month recording period (after the first month of intervention) will be analyzed for protocol compliance. This will be compared to compliance before the intervention, which will be determined by the pre-intervention survey.

CLABSI, CAUTI, and VAP data from the six months prior to the intervention will be analyzed and compared to data in the 6-month intervention recording period to determine product efficacy.

5.2 Assessment Methods

Compliance

Compliance is defined as following the protocol for disinfection of the needleless connector. In the pre-intervention period, the disinfection protocol will utilize existing institution scrub-the-hub method. Compliance in the pre-intervention period will be determined by survey.

In the intervention period, the disinfection protocol consists of using the disinfecting barrier cap on every needless connector used for accessing CVC IV lines per protocol. Compliance will be measured using observations by study personnel and/or the principal investigator, according to a schedule to ensure the absence of a shift bias. Observations will take place three times per week during the first four weeks in all intervention wards with a specially designed report form. After the first four weeks, the observations will be scheduled once per week for each intervention ward.

Prospective compliance audits will include observations on the number of needleless connectors with, and the number of needleless connectors without, disinfecting barrier caps attached. The Nurse Assistance Unit will be notified after the end of the audit about any uncapped needleless connectors or misused caps for any necessary corrections. CVCs with connectors that are being used for continuous infusion at the time of the observation will be tallied, but will not be included in the compliance rate calculation.

Infection Rates

Incidence of CLABSI, CAUTI, and VAP will be noted from existing aggregate hospital surveillance system data. The incidence will be recorded for each assigned intervention ward and for intervention ward overall by month, in the six months before the intervention and in the six-month intervention recording period.

CLABSI is defined as an occurrence of a positive blood culture when a central-line catheter has been in place two days or longer on the date of the event. The rate will be documented in terms of catheter days.

CAUTI is defined as a urinary tract infection where an indwelling urinary catheter was in place for >2 calendar days on the date of event, with day of device placement being Day 1, ***AND*** an indwelling urinary catheter was in place on the date of event or the day before. The rate will be documented in terms of catheter days.

VAP is defined as a pneumonia that occurs 48 hours after intubation, which was not incubated during the period of the patient's admission, up to 72 hours after extubation. The rate will be documented in terms of ventilator days.

5.3 Statistical Methods

5.3.1 Compliance Analyses

Compliance rates to scrub-the-hub disinfection procedures before the intervention will be determined by written survey. The target survey response rate on scrub-the-hub compliance is 70% of healthcare professionals in the intervention wards that utilize needleless connectors for patient IV access. An overall compliance rate and compliance rates per intervention ward will be determined.

Compliance rate for use of the disinfecting barrier cap on needleless connectors during the intervention recording period will be determined by weekly observations in each assigned intervention ward, which will be scheduled to ensure the absence of a shift bias. Compliance by ward, and by format of disinfecting cap (disinfecting cap strips vs. individual disinfecting caps) will also be assessed.

5.3.2 Efficacy Analyses

CLABSI

The statistical analysis for efficacy is a Poisson-regression with outcome measure rate of CLABSI per 1,000 central line days and with predictors sort of treatment (scrub the hub protocol or the disinfecting barrier cap), and variables for the time trend and the unit.

CAUTI/VAP

The statistical analysis for efficacy is a Poisson-regression with outcome measure rate of CLABSI per 1,000 central line days and with predictors

sort of treatment (scrub the hub protocol or the disinfecting barrier cap), and variables for the time trend and the unit.

CLIN-PROT-ICH-US-05-319980, version 8, update to document (Protocol Amendment 2): Protocol amended to document addition of an ad-hoc analysis of CLABSI infections both pre- and post-intervention. CLABSI infections will be further classified as those associated with mucosal barrier injury (MBI), and those that are not MBI-related, using the current CDC NHSN definition of mucosal-barrier injury laboratory-confirmed bloodstream infection (MBI-LCBI). The analysis of the classified CLABSI infections (MBI and not MBI related) will be conducted separately using the same planned analysis as the overall aggregated CLABSI infections.

6. Data Handling and Record Keeping

6.1 Study Personnel

Prior to study initiation, the Investigator must provide the following documents to 3M or its designee:

6.1.1 Signed copy of project protocol including any amendments in place prior to study initiation
6.1.2 Curriculum vitae for the Investigator
6.1.3 Ethics Committee project authorization form
6.1.4 Ethics Committee name, location and chairperson
6.1.5 Signed research agreement

6.2 Completion and Return of Case Report Forms

3M intends to use electronic data capture (eDC) software for this study. The site will be trained on the eDC software prior to study enrollment. The site will be provided with a manual, including instructions on how to complete the CRFs and how to make CRF corrections. Data may be recorded onto data collection sheets prior to data entry or may be entered directly into the eDC system. Once the forms are completed, the monitor will review the CRFs to assure accuracy and completeness. The Investigator must review and sign the CRFs for each subject in a timely fashion following completion.

6.3 Final Report

The Investigator will prepare a Final Report and submit to the Ethics Committee if required.

7. References

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7.11 Ramirez, C., Lee, A., Welch, K. Central Venous Catheter Protective Connector Caps Reduce Intraluminal Catheter-Related Infection. The Journal of the Association for Vascular Access. 2012; 17(4), 210-213.

7.12 Sweet, M. A., et al. Impact of Alcohol-Impregnated Port Protectors and Needleless Neutral Pressure Connectors on Central Line–Associated Bloodstream Infections and Contamination of Blood Cultures in an Inpatient Oncology Unit. American Journal of Infection Control. 2012; 40(10), 931-934.

8. Appendices

8.1 Retrospective Compliance Survey

Retrospective Compliance Survey for Scrub the Hub (page 1 of 2)

Date of survey:

☐☐☐☐ ☐☐ ☐☐
Year Month Date

Healthcare Professional Name: _____

During the last 6 months, how have **you** performed the following practices before accessing IV ports.

Scrub Time	Always	Usually	Some-times	Never
No scrub	☐	☐	☐	☐
< 5 seconds	☐	☐	☐	☐
≥5 - < 10 seconds	☐	☐	☐	☐
≥10 - ≤ 15 seconds	☐	☐	☐	☐
> 15 seconds	☐	☐	☐	☐

Dry time	Always	Usually	Some-times	Never
No dry	☐	☐	☐	☐
Completely dry	☐	☐	☐	☐

What is the standard in your institution?

Scrub time: _____

Whenever you had less than 10 seconds of scrub time, which of the following was most likely to be your reason? (check all that apply)

- ☐ The patient urgently needed the medication
- ☐ High patient – nurse ratio.
- ☐ In my mind, I believe 10 seconds is more than necessary.
- ☐ Another reason (text field) _____

Retrospective Compliance Survey for Scrub the Hub (page 2 of 2)

During the last 6 months, how have you observed **coworkers** performing the following practices (including CRNAs, anesthesia, nursing students, PACU staff, everybody you have observed accessing IV ports)

Scrub Time	Always	Usually	Some-times	Never
No scrub	☐	☐	☐	☐
< 5 seconds	☐	☐	☐	☐
≥5 - < 10 seconds	☐	☐	☐	☐
≥10 - ≤ 15 seconds	☐	☐	☐	☐
> 15 seconds	☐	☐	☐	☐

Dry time	Always	Usually	Some-times	Never
No dry	☐	☐	☐	☐
Completely dry	☐	☐	☐	☐

Whenever your coworkers had less than 10 seconds of scrub time, which of the following was most likely to be your reason? (check all that apply)

- ☐ The patient urgently needed the medication
- ☐ High patient – nurse ratio.
- ☐ In my mind, I believe 10 seconds is more than necessary.
- ☐ Another reason: _____